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PATENTS, TRADEMARKS, COPYRIGHTS & UNFAIR COMPETITION

March 26, 2008

Commissioner For Patents
Office of Initial Patent Examination
Customer Service Center
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Our File: TEVNHC 3.3-066
Appln. No. 10/594,861
Filing Date: December 5, 2007
Group Art Unit: 1616

Dear Sir:

We are enclosing herewith copies of the filing receipt, executed Declaration and Supplemental Application Data Sheet for the above-identified patent application.

Please note that the CITY for the third-named Applicant, Donald MacDonald, should read --Ayrshire, United Kingdom--, not "Cheshire."

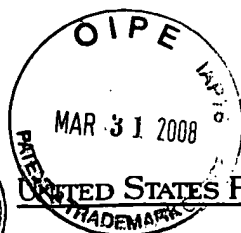
Kindly issue a corrected filing receipt for the above-identified application as soon as possible.

Sincerely yours,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP

ARNOLD H. KRUMHOLZ
Reg. No. 25,428

AHK/lis
Enclosures



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
10/594,861	12/05/2007	1616	1390	TEVNHC 3.3-066	17	3

CONFIRMATION NO. 8141

FILING RECEIPT



530

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

Date Mailed: 03/04/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Applicant(s)

Adrian Ashley, Cheshire, UNITED KINGDOM;
Paul Lamb, Cheshire, UNITED KINGDOM;
Donald MacDonald, Cheshire, UNITED KINGDOM;
John Miller, Cheshire, UNITED KINGDOM;
Martin J. Oliver, Cheshire, UNITED KINGDOM;
Mathew Pollard, Cheshire, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number 530

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US05/17292 05/17/2005

Foreign Applications

UNITED KINGDOM 0410995.5 05/17/2004

If Required, Foreign Filing License Granted: 03/01/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 10/594,861**

Projected Publication Date: 06/12/2008

Non-Publication Request: No

Early Publication Request: No

LDLK&M

MAR 06 2008

RECEIVED

Title

Heat Sterilization of Glucocorticosteroids

Preliminary Class

424

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



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Approved for use through 10/31/2002. OMB 0651-0032
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	TEVNHC 3.3-066
	First Named Inventor	Adrian Ashley
	COMPLETE IF KNOWN	
	Application Number	10/594,861
	Filing Date	September 29, 2006
	Group Art Unit	N/A
	Examiner Name	Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY)

05/17/2005

as United States Application Number or PCT International

Application No.

PCT/US2005/017292

and was amended on (MM/DD/YYYY)

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0410995.5	GB	05/17/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box +

PTO/SB/01 (03-01)
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DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to: ☒ Customer Number or Bar Code Label 000530 OR ☐ Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

Email

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any])

Adrian

Family Name
or Surname

Ashley

Inventor's
Signature

Date

20-Aug-2008

Residence: City

Cheshire

State

United Kingdom

Citizenship

United Kingdom

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

WA7 3FA

Country

United Kingdom

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any])

Paul

Family Name
or Surname

Lamb

Inventor's
Signature

Date

Residence: City

Cheshire

State

United Kingdom

Citizenship

United Kingdom

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

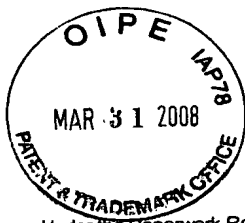
WA7 3FA

Country

United Kingdom

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

LD-537A



PTO/SB/02A (09-04)

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet
Page 1 of 1	

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Donald		MacDonald	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	United Kingdom
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
Cheshire		WA7 3FA	
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
John		Miller	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
Cheshire		WA7 3FA	
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Martin J.		Oliver	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
Cheshire		WA7 3FA	
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Mathew		Pollard	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
Cheshire		WA7 3FA	
City	State	Zip	Country



These type B and type C applications are made by the inventor.

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Approved for use through 10/31/2002 OMB 0851-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		Attorney Docket Number: TEVNH03-3-066
<input type="checkbox"/> Declaration Submitted with Initial Filing		First Named Inventor: Adrian Ashley
<input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		COMPLETE IF KNOWN
		Application Number: UNKNOWN
		Filing Date: September 29, 2006
		Group An Unit: N/A
		Examiner Name: Not Yet Assigned

As a below-named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS

(Title of the invention)

the specification of which:

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) **05/17/2005** as United States Application Number of PCT International:

Application No. **PCT/US2005/017292** and was amended on (MM/DD/YYYY) (If applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States or America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0410995-5	GB	05/17/2003	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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PTO/SB/01 (03-01)

Approved for use through 10/31/2002 OMB-0851-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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DECLARATION - Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. Customer Number 000530.

Direct all correspondence to

Customer Number
or Bar Code Label

000530

OR ☐

Correspondence address below

Name

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State

ZIP

Country

Telephone

E-mail

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued hereon.

NAME OF SOLE OR FIRST INVENTOR:



A petition has been filed for this unsigned inventor

Given Name

Adrian

Family Name

Ashley

(first and middle if any)

Inventor's

Signature

Date

Residence City

Cheshire

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United Kingdom

Country

Citizenship

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Mailing

Address

Aston Lane North, Whitehouse Vale Industrial Estate
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WA7 3FA

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Country

United Kingdom

NAME OF SECOND INVENTOR:



A petition has been filed for this unsigned inventor

Given Name

Paul

Family Name

Lamb

(first and middle if any)

Inventor's

Signature

Date

27 Oct 06

Residence City

Cheshire

State

United Kingdom

Country

Citizenship

United Kingdom

Mailing

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Preston Brook, Runcorn

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Cheshire

State

WA7 3FA

ZIP

Country

United Kingdom



Additional inventors are being named on the

1

supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

LD-537A



P/O/SB/02A (09/04)

Approved for use through 07/31/2008 - OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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DECLARATION				ADDITIONAL INVENTOR(S) Supplemental Sheet	
				Page 1 of 1	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
Donald				McDonald	
Inventor's Signature		Date			
Cheshire		United Kingdom		US	
Residence: City		State		Country	
City		State		Country	
Cheshire		WA7 3FA		United Kingdom	
Mailing Address		Aston Lane North, Whitehouse Vale Industrial Estate			
Preston Brook, Runcorn					
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
John				Miller	
Inventor's Signature		Date			
Cheshire		United Kingdom		United Kingdom	
Residence: City		State		Country	
City		State		Country	
Cheshire		WA7 3FA		United Kingdom	
Mailing Address		Aston Lane North, Whitehouse Vale Industrial Estate			
Preston Brook, Runcorn					
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
Marlin J				Oliver	
Inventor's Signature		Date			
Cheshire		United Kingdom		United Kingdom	
Residence: City		State		Country	
City		State		Country	
Cheshire		WA7 3FA		United Kingdom	
Mailing Address		Aston Lane North, Whitehouse Vale Industrial Estate			
Preston Brook, Runcorn					
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Mathew				Pollard	
Inventor's Signature		Date			
Cheshire		United Kingdom		United Kingdom	
Residence: City		State		Country	
City		State		Country	
Cheshire		WA7 3FA		United Kingdom	
Mailing Address		Aston Lane North, Whitehouse Vale Industrial Estate			
Preston Brook, Runcorn					



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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☐ Declaration
Submitted
with Initial
Filing

OR

☒ Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e))
required)

Attorney Docket Number

TEVNHC 3.3-066

First Named Inventor

Adrian Ashley

COMPLETE IF KNOWN

Application Number

10/594,861

Filing Date

September 29, 2006

Group Art Unit

N/A

Examiner Name

Not Yet Assigned

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Prior Foreign Application Numbers	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed		Certified Copy Attached?	
			YES	NO	YES	NO
0410995.5	GB	05/17/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box +

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NAME OF SOLE OR FIRST INVENTOR:



A petition has been filed for this unsigned inventor

Given Name
(first and middle (if any))

Adrian

Family Name
or Surname

Ashley

Inventor's
Signature

Date

Residence: City

Cheshire

State

United Kingdom

Country

Citizenship

United Kingdom

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

WA7 3FA

ZIP

Country

United Kingdom

NAME OF SECOND INVENTOR:



A petition has been filed for this unsigned inventor

Given Name
(first and middle (if any))

Paul

Family Name
or Surname

Lamb

Inventor's
Signature

Date

Residence: City

Cheshire

State

United Kingdom

Country

Citizenship

United Kingdom

Mailing
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Preston Brook, Runcorn

City

Cheshire

State

WA7 3FA

ZIP

Country

United Kingdom



Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

I.D-537A



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DECLARATION		ADDITIONAL INVENTOR(S) Supplemental Sheet	
		Page 1 of 1	
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Donald		MacDonald	
Inventor's Signature <i>D. MacDonald</i>		Date 04 Dec. 2007	
Residence: City	State	Country	
Cheshire		United Kingdom	United Kingdom
Mailing Address:		9 JOUR STUART ROAD, LARGES, CHESHIRE, UK, KA30 9ES	
Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
City	State	Zip	Country
Cheshire		WA7 3FA	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
John		Miller	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Cheshire		United Kingdom	United Kingdom
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn	
Cheshire		WA7 3FA	
City	State	Zip	Country
Cheshire		WA7 3FA	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Martin J.		Oliver	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Cheshire		United Kingdom	United Kingdom
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn	
Cheshire		WA7 3FA	
City	State	Zip	Country
Cheshire		WA7 3FA	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Mathew		Pollard	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
Cheshire		United Kingdom	United Kingdom
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn	
Cheshire		WA7 3FA	
City	State	Zip	Country
Cheshire		WA7 3FA	United Kingdom



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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TEVNH 3.3-066

First Named Inventor Adrian Ashley

COMPLETE IF KNOWN

Application Number UNKNOWN

Filing Date September 29, 2006

Group Art Unit N/A

Examiner Name Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS

(Title of the Invention)

the specification of which

☐ is attached hereto
OR

☒ was filed on (MM/DD/YYYY) 05/17/2005 as United States Application Number or PCT International

Application No. PCT/US2005/017292 and was amended on (MM/DD/YYYY) (if applicable).

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0410995.5	GB	05/17/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Please type a plus sign (+) inside this box: ☐

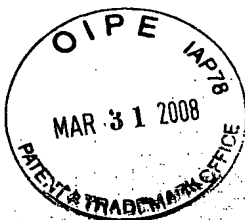
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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to:		<input checked="" type="checkbox"/> Customer Number or Bar Code Label	000530	OR	<input type="checkbox"/> Correspondence address below
Name					
Address					
City		State		ZIP	
Country		Telephone		Email	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])			Family Name or Surname		
Adrian			Ashley		
Inventor's Signature		Date			
Residence: City		State		Country	
Cheshire				United Kingdom	
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
City		State		Country	
Cheshire				United Kingdom	
ZIP		WA7 3FA			
NAME OF SECOND INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])			Family Name or Surname		
Paul			Lamb		
Inventor's Signature		Date			
Residence: City		State		Country	
Cheshire				United Kingdom	
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
City		State		Country	
Cheshire				United Kingdom	
ZIP		WA7 3FA			
<input checked="" type="checkbox"/> Additional inventors are being named on the <u>1</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.					

LD-537A



PTO/SB/02A (09-04)

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet	Page 1 of 1
--------------------	--	-------------

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Donald		McDonald	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
US			
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
City		State	Zip
Cheshire		WA7 3FA	Country
United Kingdom			
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
John		Miller	
Inventor's Signature		Date	
<i>John Miller</i>		200CT06	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
United Kingdom			
Mailing Address: Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
City		State	Zip
Cheshire		WA7 3FA	Country
United Kingdom			
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Martin J.		Oliver	
Inventor's Signature		Date	
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United Kingdom			
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United Kingdom			
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Given Name (first and middle (if any))		Family Name or Surname	
Mathew		Pollard	
Inventor's Signature		Date	
Cheshire		United Kingdom	
Residence: City	State	Country	Citizenship
United Kingdom			
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United Kingdom			



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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	TEVNHHC 3.3-066
	First Named Inventor	Adrian Ashley
	COMPLETE IF KNOWN	
	Application Number	UNKNOWN
	Filing Date	September 29, 2006
	Group Art Unit	N/A
	Examiner Name	Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS

(Title of the invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 05/17/2005 as United States Application Number or PCT International

Application No. PCT/US2005/017292 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0410995.5	GB	05/17/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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State

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Country

Telephone

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle (if any))

Adrian

Family Name
or Surname

Ashley

Inventor's
Signature

Date

Residence: City
Cheshire

State

Country
United Kingdom

Citizenship
United Kingdom

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

ZIP
WA7 3FA

Country
United Kingdom

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle (if any))

Paul

Family Name
or Surname

Lamb

Inventor's
Signature

Date

Residence: City
Cheshire

State

Country
United Kingdom

Citizenship
United Kingdom

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

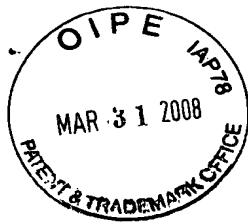
ZIP
WA7 3FA

Country
United Kingdom

☒

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				Page 1 of 1	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
Donald				McDonald	
Inventor's Signature				Date	
Cheshire				United Kingdom	
Residence: City				Citizenship	
State				US	
Country					
Mailing Address:					
Aston Lane North, Whitehouse Vale Industrial Estate					
Preston Brook, Runcom					
City				Country	
Cheshire				United Kingdom	
State					
Zip				WA7 3FA	
Country					
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
John				Miller	
Inventor's Signature				Date	
Cheshire				United Kingdom	
Residence: City				Citizenship	
State				United Kingdom	
Country					
Mailing Address:					
Aston Lane North, Whitehouse Vale Industrial Estate					
Preston Brook, Runcom					
City				Country	
Cheshire				United Kingdom	
State					
Zip				WA7 3FA	
Country					
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
Martin J.				Oliver	
Inventor's Signature				Date	
Cheshire				United Kingdom	
Residence: City				Citizenship	
State				United Kingdom	
Country					
Mailing Address:					
Aston Lane North, Whitehouse Vale Industrial Estate					
Preston Brook, Runcom					
City				Country	
Cheshire				United Kingdom	
State					
Zip				WA7 3FA	
Country					
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))				Family Name or Surname	
Mathew				Pollard	
Inventor's Signature				Date	
Cheshire				United Kingdom	
Residence: City				Citizenship	
State				United Kingdom	
Country					
Mailing Address:					
Aston Lane North, Whitehouse Vale Industrial Estate					
Preston Brook, Runcom					
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Cheshire				United Kingdom	
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	First Named Inventor	Adrian Ashley
	COMPLETE IF KNOWN	
	Application Number	UNKNOWN
	Filing Date	September 29, 2006
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Given Name
(first and middle [if any])

Adrian

Family Name
or Surname

Ashley

Inventor's
Signature

Date

Residence: City

Cheshire

State

United Kingdom

Country

United Kingdom

Citizenship

Mailing
Address:

Aston Lane North, Whitehouse Vale Industrial Estate
Preston Brook, Runcorn

City

Cheshire

State

WA7 3FA

ZIP

United Kingdom

Country

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any])

Paul

Family Name
or Surname

Lamb

Inventor's
Signature

Date

Residence: City

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Inventor's Signature		Date			
Cheshire		United Kingdom		US	
Residence: City		State		Country	
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Cheshire		WA7 3FA		United Kingdom	
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Country					
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John			Miller		
Inventor's Signature		Date			
Cheshire		United Kingdom		United Kingdom	
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Martin J.			Oliver		
Inventor's Signature		Date			
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Given Name (first and middle (if any))			Family Name or Surname		
Mathew			Pollard		
Inventor's Signature		Date			
<i>M. Pollard</i>		6 Nov 2006			
Cheshire		United Kingdom		United Kingdom	
Residence: City		State		Country	
Mailing Address:		Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn			
Cheshire		WA7 3FA		United Kingdom	
City		State		Zip	
Country					



Supplemental Application Data Sheet

Application Information

Application number::	<u>10/594,861</u>
Filing Date::	<u>09/29/06</u>
Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	N/A
CD-ROM or CD-R?::	None
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Title::	HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS
Attorney Docket Number::	TEVNHC 3.3-066
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	1
Total Drawing Sheets::	4
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	United Kingdom
Status::	Full Capacity
Given Name::	Adrian
Family Name::	Ashley
City of Residence::	Cheshire
Country of Residence::	United Kingdom
Street of mailing address::	Aston Lane North, Whitehouse Vale Industrial Estate

	Preston Brook, Runcorn
City of mailing address::	Cheshire
Country of mailing address::	United Kingdom
Postal or Zip Code of mailing address::	WA7 3FA
Applicant Authority Type::	Inventor
Primary Citizenship Country::	United Kingdom
Status::	Full Capacity
Given Name::	Paul
Family Name::	Lamb
City of Residence::	Cheshire
Country of Residence::	United Kingdom
Street of mailing address::	Aston Lane North, Whitehouse Vale Industrial Estate Preston Brook, Runcorn
City of mailing address::	Cheshire
Country of mailing address::	United Kingdom
Postal or Zip Code of mailing address::	WA7 3FA
Applicant Authority Type::	<u>Inventor</u>
Primary Citizenship Country::	<u>United Kingdom</u>
Status::	<u>Full Capacity</u>
Given Name::	<u>Donald</u>
Family Name::	<u>MacDonald</u>
City of Residence::	<u>Ayrshire</u>
Country of Residence::	<u>United Kingdom</u>
Street of mailing address::	<u>9 Mount Stuart Road</u> <u>Largs</u>
City of mailing address::	<u>Ayrshire</u>
Country of mailing address::	<u>United Kingdom</u>
Postal or Zip Code of mailing address::	<u>KA30 9ES</u>

Applicant Authority Type:: Inventor
Primary Citizenship Country:: United Kingdom
Status:: Full Capacity
Given Name:: John
Family Name:: Miller
City of Residence:: Cheshire
Country of Residence:: United Kingdom
Street of mailing address:: Aston Lane North, Whitehouse Vale
Industrial Estate
Preston Brook, Runcorn
City of mailing address:: Cheshire
Country of mailing address:: United Kingdom
Postal or Zip Code of mailing address:: WA7 3FA

Applicant Authority Type:: Inventor
Primary Citizenship Country:: United Kingdom
Status:: Full Capacity
Given Name:: Martin
Middle Name:: J.
Family Name:: Oliver
City of Residence:: Cheshire
Country of Residence:: United Kingdom
Street of mailing address:: Aston Lane North, Whitehouse Vale
Industrial Estate
Preston Brook, Runcorn
City of mailing address:: Cheshire
Country of mailing address:: United Kingdom
Postal or Zip Code of mailing address:: WA7 3FA

Applicant Authority Type:: Inventor

Primary Citizenship Country:: United Kingdom
Status:: Full Capacity
Given Name:: Mathew
Family Name:: Pollard
City of Residence:: Cheshire
Country of Residence:: United Kingdom
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Industrial Estate
Preston Brook, Runcorn
City of mailing address:: Cheshire
Country of mailing address:: United Kingdom
Postal or Zip Code of mailing address:: WA7 3FA

Applicant Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Full Capacity
Given Name:: Donald
Family Name:: McDonald
City of Residence:: Cheshire
Country of Residence:: United Kingdom
Street of mailing address:: Aston Lane North, Whitehouse Vale
Industrial Estate
Preston Brook, Runcorn
City of mailing address:: Cheshire
Country of mailing address:: United Kingdom
Postal or Zip Code of mailing address:: WA7 3FA

Correspondence Information

Correspondence Customer Number:: 000530

Representative Information

Representative Customer Number:: 000530

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National Stage of	PCT/US2005/017292	05/17/05

Foreign Priority Information

Country::	Application number::	Filing Date::	Priority Claimed::
United Kingdom	0410995.5	05/17/04	Yes

Assignee Information

Assignee name:: Norton Healthcare Ltd
Street of mailing address:: Albert Basin, Royal Docks
City of mailing address:: London
Country of mailing address:: United Kingdom
Postal or Zip Code of mailing address:: E16 2QJ